PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Kisqali and Kisqali Femara Co-Pack Prior Authorization Policy
- Kisqali® (ribociclib tablets – Novartis)
- Kisqali® Femara® Co-Pack (ribociclib tablets; letrozole tablets – Novartis)

REVIEW DATE: 02/21/2024; selected revision 10/16/2024

OVERVIEW

Kisqali, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated for the treatment of hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative breast cancer in adults in the following settings:[1-3]

- **Early Breast Cancer:** Kisqali, in combination with an aromatase inhibitor, and Kisqali Femara Co-Pack are indicated for the adjuvant treatment of stage II and III early breast cancer at high risk of recurrence.
- **Advanced or Metastatic Breast Cancer:** In combination with an aromatase inhibitor (AI) as initial endocrine-based therapy;
- **Advanced or Metastatic Breast Cancer:** Kisqali (not Co-Pack) in combination with fulvestrant as initial endocrine based therapy or following disease progression on endocrine therapy;
- Kisqali Femara Co-Pack has the same indications with AI, letrozole, included.

According to the prescribing information, in pre/perimenopausal women or men treated with the combination of Kisqali and an aromatase inhibitor or fulvestrant, a concurrent gonadotropin-releasing hormone (GnRH) agonist should be administered according to current clinical practice standards.[1]

Guidelines

Kisqali is discussed in in guidelines from National Comprehensive Cancer Network (NCCN):

- **Breast Cancer**: NCCN guidelines (version 1.2024 – January 25, 2024) recommends Kisqali + AI or fulvestrant as a first-line "Preferred Regimen" for HR+ and HER2-negative recurrent unresectable (local or regional) or Stage IV disease in postmenopausal women or premenopausal patient receiving ovarian ablation or suppression (category 1).[3,4] The guidelines state in a footnote that in phase III randomized controlled trials, Kisqali + endocrine therapy has shown overall survival benefit in the first-line setting. CDK4/6 inhibitor + fulvestrant is recommended as a "Preferred Regimen" for second- and subsequent-line therapy, if CDK4/6 inhibitor was not previously used (category 1). However, the guidelines also state in a footnote that if there is disease progression on Ibrance® (palbociclib tablets or capsules), there are limited data to support the use of Kisqali in the second-line setting.[3,4] The guidelines state that in phase III randomized controlled trials, fulvestrant in combination with a CDK4/6 inhibitor has shown overall survival benefit in the second-line setting. For men with breast cancer, the compendium recommends they be treated similarly to postmenopausal women, except that the use of an AI is ineffective without concomitant suppression of testicular steroidogenesis.[4]
- **Endometrial Cancer**: NCCN uterine neoplasms guidelines (version 1.2024 – September 20, 2023) recommend Kisqali in combination with letrozole for recurrent or metastatic endometrial carcinoma for estrogen receptor (ER)-positive tumors (category 2A).[5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Kisqali and Kisqali Femara Co-Pack. All approvals are provided for the duration noted below. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression; men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Kisqali is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Breast Cancer in Women***. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** As per the prescriber, medication is used as adjuvant treatment for early breast cancer (stage II or III) at high risk of recurrence; OR
     - **ii.** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has hormone receptor-positive (HR+) [i.e., estrogen receptor-positive {ER+} and/or progesterone receptor-positive {PR+}] disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   - **E)** Patient meets ONE of the following (i or ii):
     - **i.** Patient is postmenopausal; OR
     - **ii.** Patient is pre/perimenopausal and meets ONE of the following (a or b):
       - **a)** Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
         Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant).
       - **b)** Patient has had surgical bilateral oophorectomy or ovarian irradiation; AND
   - **F)** Patient meets ONE of the following (i or ii):
     - **i.** Kisqali will be used in combination with anastrozole, exemestane, or letrozole; OR
     - **ii.** Kisqali will be used in combination with fulvestrant.

   ***** Refer to the Policy Statement.

2. **Breast Cancer in Men*.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** As per the prescriber, the medication is used as adjuvant treatment for early breast cancer (stage II or III) at high risk of recurrence; OR
     - **ii.** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has hormone receptor-positive (HR+) [i.e., estrogen receptor-positive {ER+} and/or progesterone receptor-positive {PR+}] disease; AND

D) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
E) Patient is receiving a gonadotropin-releasing hormone (GnRH) analog; AND
Note: Examples of GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).
F) Patient meets ONE of the following (i or ii):
i. Kisqali will be used in combination with anastrozole, exemestane, or letrozole; OR
ii. Kisqali will be used in combination with fulvestrant.

***** Refer to the Policy Statement.

Other Uses with Supportive Evidence

3. Endometrial Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has recurrent or metastatic disease; AND
C) Patient has estrogen receptor (ER)-positive tumors; AND
D) Kisqali will be used in combination with letrozole.

II. Coverage of Kisqali Femara Co-Pack is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Breast Cancer in Women*. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
i. As per the prescriber, medication is used as adjuvant treatment for early breast cancer (stage II or III) at high risk of recurrence; OR
ii. Patient has recurrent or metastatic disease; AND
C) Patient has hormone receptor-positive (HR+) [i.e., estrogen receptor-positive {ER+} and/or progesterone receptor-positive {PR+}] disease; AND
D) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
E) Patient meets ONE of the following (i or ii):
i. Patient is postmenopausal OR
ii. Patient is pre/perimenopausal and meets ONE of the following (a or b):
a) Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant).
b) Patient has had surgical bilateral oophorectomy or ovarian irradiation.

***** Refer to the Policy Statement.

2 Breast Cancer in Men*. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i or ii):
  i. As per the prescriber, medication is used as adjuvant treatment for early breast cancer (stage II or III) at high risk of recurrence; OR
  ii. Patient has recurrent or metastatic disease; AND
C) Patient has hormone receptor-positive (HR+) [i.e., estrogen receptor-positive {ER+} and/or progesterone receptor-positive {PR+}] disease; AND
D) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
E) Patient is receiving a gonadotropin-releasing hormone (GnRH) analog.
Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).

***** Refer to the Policy Statement.

Other Uses with Supportive Evidence

3. Endometrial Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient has recurrent or metastatic disease; AND
C) Patient has estrogen receptor (ER)-positive tumors.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Kisqali or Kisqali Femara Co-Pack is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Kisqali® tablets [prescribing information]. East Hanover, NJ: Novartis; September 2024.
2. Kisqali® Femara® Co-Pack tablets [prescribing information]. East Hanover, NJ: Novartis; September 2024.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – January 25, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 19, 2024.
4. The NCCN Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Search term: ribociclib. Accessed on February 19, 2024.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – September 20, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 19, 2024.